Author's response to reviews

Title: Decisions about participation in RCTs: The role of conditional altruism

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Author's response to reviews: see over
Dear Editor

**MS: 8347989362602227**

*Decisions about participation in RCTs: The role of conditional altruism*

*Sharon K McCann, Marion K Campbell and Vikki A Entwistle*

We thank the reviewers for their thoughtful comments. These have encouraged us to undertake a substantial revision of the manuscript. We have highlighted (in yellow) the new and substantially edited sections of text on our revised submission. We have attempted to address each of the points raised by the reviewers in turn and list our responses below:

**Reviewer:** Susan Bull  
**Reviewer's report:**  
- Major Compulsory Revisions  
  None  
- Minor Essential Revisions  
  1. In the methods section it would be useful to have some idea of the contents of the topic guided schedule; for the interviews and an idea about whether these topics changed over time as data was collected and analysed. If word limits are a consideration the paragraph beginning In centre A, SM attended; could perhaps be deleted.

  **We have now included more detail on the contents of the topic guide in the methods section**

  2. I realize this paper is going into a primarily quantitative journal; but nonetheless in the results section some topics have been selected for discussion; it would be useful to include some context or indication of the richness of the data as well. For example, under (a) initial inclination to participate; what proportion of people (a few, some, most?) indicated an inclination to help others. What other factors contributed to / acted against the initial inclination? Under (b) potential to benefit personally and (c) personal concerns; can there be some indication of how frequently people mentioned these potentials. Where there any unusual factors only reported by a few people?

  **We would prefer not to explicitly quantify numbers of responders. Our primary reasoning for this is that this qualitative study aimed to explore the kinds of experiences and views people have of trial participation, and not to assess their frequency or distribution. The numbers of respondents are so small that descriptions in terms of distributions of responses would be inappropriate. We have, however, clarified situations where no respondents or all respondents gave similar opinions.**
3. In the results section; the paragraph ending; Indeed several quite clearly confirmed to clinicians that they had no preference or were undecided; it would be useful to know if these were also the ones who expressed the interest in receiving surgery during the interviews

*We have clarified this in the results section.*

4. With figure 1; please clarify if this just refers to people entering the randomization arm of the trial (rather than choosing a treatment arm).

*The diagram summarises the factors and considerations that influence people’s decisions about whether or not to enter the randomized arms of the trial. We have amended the title to reflect this. We have also amended the figure to reflect other referees comments (see below).*

**- Discretionary Revisions**

5. In the results section; the two quotes from people hoping to be allocated to surgical treatment don’t seem to add much to each other; perhaps just one could be used.

*We have deleted one of the quotes.*

6 The discussion seems to move from what motivations are to communication requirements given motivations to participate. In the discussion it might be worth making more explicit the argument that I think is underlying your comments; i.e. for consent to be valid, people need info about (and arguably understanding of) topics of most importance to their decisions. Risks and benefits are important to decision-making therefore need to think how best to explain them (and have two-way consent processes so can identify participants; misunderstandings and address them).

*We have re-written the discussion section to better reflect our arguments.*

7. In figure 1 the final two boxes may be best combined as a single box entitled decision whether or not to participate in the (randomisation arm/ any arm of the reflux trial); and the between arrows of the two boxes above it (both beginning initial inclination) could be deleted.

*As indicated above we have amended the figure in an attempt to make it clearer.*
Reviewer: Katie featherstone

Reviewer's report:
This is a well written and competent paper. However, I do have a number of reservations with the thrust of this paper that need to be dealt with.

Major compulsory revisions-
On reading – the title, introduction and discussion leads the reader to assume the paper is about ‘altruism’- however, when it gets to the results section, this doesn’t seem to be the case- this appears to be about perceived benefits and disadvantages of participation. I think the main issue with this paper is finding the focus and story- at present it doesn’t really tell us anything new.

We have amended the title to “Reasons for participating in RCTs; conditional altruism and considerations for self” to more explicitly identify the content of the paper. We have also added further paragraphs to the introduction to more explicitly lay out the main focus and thrust of our study.

I am not convinced the focus on altruism follows from the results section- to justify this the analysis needs to provide a more detailed account of its role. However, I am not convinced altruism plays a significant role in individuals decisions to participate in trials- and this paper doesn’t provide me with any evidence that it does. Having carried out a large amount of fieldwork and written in the field I have predominantly found that personal benefits and preferences for a particular treatment are key driving forces and I suggest that these are key motivations in this trial. This paper may also benefit from being a little more specific in focus- this trial looks at a preference trial- perhaps experiences of participation in this type of trial would be an interesting focus. It may also be useful to focus on participants or non-participants- this is a short paper and I think including all groups and data sets may be too much and has lead to a rather surface paper.

In our revision, we have clarified and strengthened our account of people’s initial thoughts and perspectives on trial participation. We have sought to explain the concept of conditional altruism more clearly, explaining how this reflects the idea that consideration for others was not the sole driver in reasons for participation. We have also sought to further highlight some of the issues specific to this trial eg the impact of the preference design.

What is the aim of the paper- to provide ways to improve recruitment? Please set out aims of the paper more clearly – it seems to drift across a few interlinked themes. The authors discuss ‘non-altruistic as well as altruistic motivations as important’ –why divide altruism away from wider motivation?
We have now sought to further clarify the aims of our paper. The paper has sought to develop the insights that consideration for self have on recruitment processes (and especially for recruitment to patient preference trials) and examined the implications of these for trialists. This is reflected in the revised title, the reframing of the introduction and the tightening up of the discussion section. We have replaced the phrase the reviewer cited here.

Background
The review of the literature examining patients experiences of recruitment particularly the qualitative literature is rather surface- I am not convinced that the authors have really tried to engage properly with this literature it is summarized to such an extreme that it doesn't really tell the reader anything- if they engaged, I think they would achieve a better story.

We had actually undertaken a full meta-ethnography of relevant papers alongside this primary research. However, as this is being written up separately, we had only provided a summary of some of the key papers within this paper. We have now explicitly alluded to this in the paper and have listed all the papers identified for inclusion in our meta-ethnography (and more). This shows that we did indeed identify the papers which this reviewer thought we had not considered – see point below – and we hope this reassures the reviewer that we were indeed cognizant of the wider literature.

The detailed qualitative studies in this field (some of which are cited here) are trying to uncover the complexities involved in understanding and participating in clinical trials- the authors should do this literature justice rather than glossing over them. In addition, the authors have missed some key references- see Snowdon et al (social science and medicine) who is a key author in the field. The authors should also examine in more detail some of the papers already cited particularly the papers by Donovan and Featherstone.

See response to the point above.

They say that ‘altruism’ is a clear theme emerging from research in the field however, I would not agree- the authors need to examine the varying quality and methodologies employed by the studies in this field and engage in a more selective way with the literature.

We have now explained that while it is widely assumed that altruistic-type motives are important for trial participation (see first paragraph of Background section), a number of qualitative investigations have
generated insights into factors that influence participation, and a variety of considerations relating both to others and to the potential participants themselves have emerged as important (see third paragraph of Background section). We have not included our quality appraisals of particular studies in this paper because we think they are more appropriately included with the meta-ethnographic synthesis, but we have included only the more rigorous papers among the studies cited in this paper.

More details of the trial and the condition are needed to enable the reader to put it in context. Is this a preference trial? If so, this needs to be discussed as a methodology and that this is an unusual trial and not standard – it is also a surgical trial, which has specific issues. Also perhaps a section on what information patients received about the trial. The observational data could be used here to provide the context- what happened in these consultations? This is also a key aspect of recruitment missing in the wider literature.

We have added further detail to the section describing the REFLUX trial including aspects on the design, the treatments etc. We have also included more detail of the observational field notes within our results section to shed light on the consultation processes.

In addition, I didn’t really understand from the description what GORD is- please explain for a wider audience- life expectancy? Effect on quality of life? Treatment?

As indicated above, we have added more detail on the clinical condition.

Results
Table 1- I am not sure what table one adds to the readers understanding- I would prefer the summary of participants in a sentence in the methods section.

We have added a brief summary description of the participants at the start of the results section (some of the information on which it is based was derived from what participants told us in interviews). We would prefer to retain Table 1 as it describes more fully the characteristics of the patients who contributed to this research.

Figure 1- I do not like this table and would like it removed- I don’t think that the complexity of patients experiences can be reduced to a flow chart and do not think that this is an appropriate representation of patients decision-making- do patients really divide ‘benefits’ and ‘disadvantages’ in such a systematic way. This is not consistent with the methodological approach.

As we have alluded to in the response to the previous reviewer, we have amended and refined Figure 1. We do, however, think it is useful to
summarise the types of issues that contributed to patients’ reasoning as to why to participate (or not) in the RCT. We have relabeled the figure to indicate that it is a schematic overview of the categories of consideration that featured in accounts.

I am not convinced by the themes- what is an ‘initial inclination to participate’? - is this about motivation and why is it important- and how do you know when this is recalled during a post-recruitment interview? Similarly, dividing the following sections into perceived benefits and disadvantages feels a little simplistic. The section on ‘benefits’- to me this reads as- They want access to better treatment/specialists and they want access to their treatment preference

*We have sought in the methods section to give greater clarity as to the process by which we organized the material in the findings section. Initial open codes were grouped according to the stages of the trial recruitment processes they referred to and/or thematic categories related to types of experiences, considerations or reasons that seemed salient to the participants.*

Generally there is poor integration of observational data- if you are using this data set- which I encourage you to do- you do need to provide extracts of field notes or provide a description of the encounter, not just refer generally to the observation findings, for example -‘Observation notes from this man’s and other’s trial recruitment consultation suggest that in practice, potential participants did not ask many questions about their own condition or current treatment, but none of them expressed disappointment with this consultation.’ It is not enough to give a general overview of the observational data, it reads a little like anecdotal evidence rather than data- so a more robust use of this method please. I would also hope that this data set will add a more detailed context in which the interview results can be situated.

*In our revision, we have sought to provide a stronger integration of the observational data. We have used them to describe the range of recruitment consultations and we systematically examined field notes for evidence that either backs-up or contradicts perspectives raised in the interviews.*

Generally, this is a rather ‘surface’ analysis- more analysis of the extracts- what does it mean? Also a little more detail- for example, statements like ‘a couple of interviewees’ is a little chatty in tone and not appropriate. I am not convinced that the themes presented here really tell us anything new- the authors need to look at the qualitative papers in the field already and see how they can develop or move on their findings- this paper fails to deal or acknowledge the complexity of peoples decision-making and their rationales for participation or not.
As alluded to in the responses above, we have sought to add depth to the detail provided in the paper through greater integration of observation notes and through cross-reference to the range of previous studies. We have sought to sharpen up the tone of the paper throughout.

In addition, I would prefer longer data extracts that are analysed in more detail but less of them. A one or two line extract does not tell us anything.

Reflecting our main audience, and the primary audience of the journal (ie trialists) our main aim was to use the quotes as illustrative examples of the points raised in the paper.

I find the main thrust of this paper too simplistic- ‘The main findings of this study are that an inclination to help others or contribute to a collective general good can positively predispose people towards participation in a clinical trial, but that the formal decision about participation is then additionally influenced by considerations of the implications of participation for themselves personally.’ It feels as though the authors have referred to the literature, but haven’t engaged with it What does this tell us? Do people really have an ‘inclination’ followed by a ‘formal decision’?

We trust that our responses above and the substantial revision of the paper address these concerns.

Discussion and conclusion
Given the nature of the journal, the suggestions for trialist at the end of the paper are a bit predictable and weak- I think some detailed practical advice perhaps aimed at those running preference trials may be more appropriate and useful

In the revision we have sought to develop the recommendations for trialists at the end of the paper, particularly with regard to the possible content of trial consultations. These now pick up more clearly on the particular issues raised by this study.

In addition, given my above comments, I do not think they can justify the section on the gift relationship without a lot more work examining this within the analysis section.

We have removed the section on the gift relationship.

Minor essential revisions-
Methods
Details of the number of patients recruited onto the trial and for each of the trial arms, dates of the trial, how many centers? The sub-study examines patients from two centers, but how were they chosen and what were the other centers?
We have added this detail.

‘A combination of observational and interview methods were adopted [29-31]’- is this ethnographic? Why were these methods chosen- I think for a paper within a journal such as this, a justification of the methods- why they are used to explore this topic and details of how the data was analysed is vitally important- this allows readers from a wide range of audiences to judge the quality of the paper.

We have sought to explain more clearly in the methods section how we conducted observations and interviews and how we used them.

The methods section is already long so I would encourage the authors to focus on tightly summarizing the key features of the methods- numbers, sample etc and concentrate on providing readers with a robust description of the appropriateness of the methods and how they link to the aims of the study.

We have been guided by the editor that space considerations is not an issue so have not explicitly addressed this point in the revision.
Reviewer: Jenny L Donovan
Reviewer’s report:
This is a very nicely written paper. It addresses an important question underlying why patients take part in RCTs. The finding is original and a contribution to the literature in adding a degree of subtlety to the often described finding that participants are motivated by altruism. This paper finds that altruism is important, but adds that it is not the only motivation for participation as some element of perceived personal benefit is also involved. The methods of the study are described thoroughly and the data are presented well. The title and abstract are suitable

- Major Compulsory Revisions
None

- Minor Essential Revisions
The authors should:
1. Improve the rather clumsy sentence in the abstract: “Enactment of the tendency to … themselves”.

   This has been re-written.

2. Provide a reference to support the qualitative research methods used. The description of the data analysis on page 7 is adequate although “&” should be replaced by text, and a reference to the method should be provided

   We have added a reference to support our methodological approach (Pope et al, 2000) and have corrected the text.

3. Within the discussion, provide a short section on the possible limitations of the current research.

   We have added a new section on strengths and weaknesses to the discussion.

- Discretionary Revisions
The authors might like to consider the following minor points that might improve the manuscript:
1. On page 5, the issue of limiting the patient preference group is mentioned. This could be reflected on in the discussion in terms of the effect this might have had on the sample interviewed and observed. It is not clear why this quota was applied.

   We have addressed this in the discussion section.
2. On page 8, before the section (a) initial inclination to participate, it would be helpful to the reader to have a short paragraph explaining how the data moved from analysis to these themes, and an overview of how the themes were derived and organized.

   As indicated in our responses to the other reviewers, we have added greater detail to the methods section as to how we organized our study material.

3. The discussion includes several interesting and important issues. The authors might like to consider the recently published paper by Wade et al (It's not just what you say, it's also how you say it: Opening the ‘black box’ of informed consent appointments in randomized controlled trials. Social Science and Medicine 2009, 68, 11, 2018-2028) which addresses some similar issues.

   We thank the reviewer for highlighting this recent paper to us. We have incorporated it into the discussion section where we discuss the implications of our research for how trial consultations might better be delivered.

We trust that these revisions are acceptable and look forward to hearing from you.

Yours sincerely

Marion K Campbell, on behalf of all authors